REMARKS

Applicants have cancelled claim 11 without prejudice expressly reserving the right to pursue the subject matter of the cancelled claim in one or more continuation applications. Applicants have amended claims 13-17 to depend on claim 12. Applicants have amended the Markush group recited in claim 12.

Claim 12 is objected to for purportedly reciting an improper Markush group. Amended claim 12 recites a proper Markush group thus obviating the objection.

Claims 11-17 stand rejected under 35 U.S.C. 112, second paragraph for purportedly failing to particularly point out and distinctly claim the subject matter of the invention. Applicants respectfully disagree.

The Examiner states that the recitation of "treating obesity" recited in the preamble of claim 11 may be implied as what is meant for "an effective dosage of PPARα agonist" but contends that this is implied at best and an implied limitation is not clear and concise as required under 112, second paragraph (Office Action page 3). Applicants respectfully disagree. Whether a claim is invalid for indefiniteness requires a determination whether those skilled in the art would understand what is claimed when the claim is read in light of the specification. One of skill in the art with Applicants' specification in hand would clearly understand what is claimed. Nonetheless, in the interest of expediting prosecution, Applicants have cancelled claim 11 without prejudice, and have amended claim 12 such that the PPARα agonist is defined with particularity and such that the effective dosage of a PPARα agonist and the effective dosage of metformin are effective for the treatment of obesity.

The Examiner also contends there is insufficient antecedent basis in claim 11 for the phrase "the effective dosage of metformin" recited in claim 15. As

amended claim 15 depends on claim 12, which provides the appropriate antecedent basis for the phrase "the effective dosage of metformin."

In view of the amendments to the claims and the foregoing remarks Applicants request the Examiner to reconsider and withdraw the rejection of the claims under 35 U.S.C. 112, second paragraph.

Claims 12-13 stand rejected under 35 U.S.C. 112, first paragraph for purportedly failing to comply with the written description requirement. In particular the Examiner contends that the specification provides insufficient written description for the genus of fibric acid derivatives or esters of fibric acid derivatives. Applicants respectfully disagree but in the interest of expediting prosecution, Applicants have amended claim 12 such that the terms "fibric acid derivatives" and "esters of fibric acid derivatives" are not recited.

The Examiner acknowledges that the specification discloses examples of fibrate compounds such as gemfibrozil, fenofibrate, bezafibrate, clofibrate and ciprofibrate. Amended claim 12 describes the PPARα agonist as selected from the group consisting of fenofibrate, a gemfibrozil, fenofibric acid, bezafibrate, ciprofibrate, a pharmaceutically acceptable salt of gemfibrozil, a pharmaceutically acceptable salt of fenofibric acid, a pharmaceutically acceptable salt of bezafibrate, and a pharmaceutically acceptable salt of ciprofibrate.

In view of the foregoing remarks, Applicants request that the Examiner reconsider and withdraw the rejection of claims 12 and 13 for purportedly failing to satisfy the written description requirement of 35 U.S.C. 112, first paragraph.

Claims 11, 14 and 16-17 stand rejected under 35 U.S.C. 102(e) for purportedly being anticipated by Liu et al. (US PGPUB 2002/0173663, filing date Aug. 11, 2001)("Liu"). Applicants respectfully disagree.

Applicants have cancelled claim 11 without prejudice and amended claims 14 and 17 such that they depend on claim 12, which is not rejected under 35 U.S.C. 102(e). In view of the foregoing remarks and amendments to the claims Applicants request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. 102(e).

Claims 11-17 stand rejected under 35 U.S.C. 103(a) for purportedly being unpatentable over Pan et al. (US Patent No. 5,190,970)("Pan") in view of Beisswenger et al. (US PGPUB 2001/0031790)("Beisswenger") and Rink et al. (US Patent No. 5,739,106)("Rink"). Applicants respectfully disagree. Pan does not disclose a treatment for obesity. Beisswenger also does not disclose treatments for obesity: Furthermore, Beisswenger relates to treating complications resulting from diabetes, such as retinal and renal diseases, and as such one of skill in the art interested in developing a treatment for obesity would not have considered Beisswenger. Rick is merely an invitation to experiment and fails to provide the motivation necessary to combine and modify the teachings of the cited art to generate the claimed invention. As such, the cited references do not render the claimed invention obvious.

> Determination of obviousness can not be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention.
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> *ATD Corp. v. Lydall, Inc.* 48 USPQ2d 1321 (Fed. Cir. 1998)

> Although couched in terms of combining teachings found in the prior art, the same inquiry must be carried out in the context of a purported obvious "modification" of the prior art. The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.
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> *In re Fritch* 23 USPQ2d 1780(1992)

Applicants' claimed method is for the treatment of obesity by coadministering metformin and a defined subset of PPARα agonists. The

Examiner contends that Pan teaches fenofibrate tablets of 250 mg for treating type II diabetes, but acknowledges that Pan (i) fails to teach the combination of fenofibrate and metformin and (ii) fails to teach the treatment of obesity. The Examiner contends that Beisswenger discloses metformin for treating type II diabetes using dosage of 1000 mg per day. The Examiner further contends that it would have been obvious for one of skill in the art to combine fenofribrate and metformin for treating type II diabetes, motivated by their having been purportedly taught by the prior art to be useful in treating type II diabetes "consonant with the reasoning of the cited case law" (Office Action, page 8). The Examiner, citing Rink, concludes that one having ordinary skill in the art would have been motivated by Rink to practice the combined therapy for treating type II diabetes, i.e., the co-administration of fenofibrate and metformin, to treat obesity with a reasonable expectation of success. The Examiner comes to her conclusion because, the Examiner contends that, (1) Rink discloses that obesity and type II diabetes are associated in both clinical and epidemiological studies, and (2) Rink teaches that weight reduction is often recommended as a first course of action for treating patients suffering from type II diabetes. Applicants respectfully disagree with the Examiner's reasoning and conclusion.

Rink's teaching that obesity and type II diabetes are associated in clinical and epidemiological studies does not establish a causal link between obesity and diabetes. In addition, Rink's teaching that weight reduction is often a recommended course of action for treating type II diabetes does not teach or suggest that the converse is true, i.e. that treating patients for type II diabetes is the recommended course of action for treating for obesity. After all, not all obese patients have type II diabetes and not all patients with type II diabetes are obese. Furthermore, Rink states:

> Weight reduction is often recommended as the first course of action of patients suffering from Type II diabetes mellitus, hypertension, hypercholesterolemia, coronary artery heart disease, gout and osteoarthritis.
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> (Col. 1, lines 43-47).

If one were to accept the Examiner's reasoning, any compound useful in the treatment of hypertension, hypercholesterolemia, coronary artery heart disease, gout and osteoarthritis would also be obvious treatments for obesity. Rink also states "there are relatively few therapeutic tools which can be employed by a physician to accomplish weight loss in patients."(Col. 1 lines 48-50). Rink does not disclose the "relatively few therapeutic tools." As such, Rink merely presents an invitation to experiment and does not provide the motivation for one of skill in the art to combine the cited references and modify their teachings as suggested by the Examiner to generate Applicants' claimed method.

The foregoing remarks demonstrate that none of the cited references teach or suggest fenofibrate or metromin, alone or together, have any effect on obesity. The foregoing remarks also demonstrate that none of the references provide the motivation for one of skill in the art to co-administer particular compounds, i.e., metformin and a defined subset of PPARα agonists, to treat obesity. The only suggestion for the use of metformin and fenofibrate in the treatment of obesity is found in Applicants' own specification; Such is not sufficient to support a rejection under 35 U.S.C. 103(a). There must be some reason or suggestion , in the cited art for selecting the procedures used, other than the knowledge learned from the Applicants own disclosure. See *In re Dow Chemical Co.* 5 USPQ 2d 1529,1532 (Fed Cir. 1988). Therefore, the combination of Pan, Beisswenger and Rink fail to render Applicants' invention obvious.

In view of the foregoing remarks, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. 103(a).

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #102717.58257US).

Respectfully submitted,

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